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Applicants: David A. Edwards and Jeffrey S. Hrkach

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Request for Reconsideration and Petition under 37 CFR 1.181

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Reply under 37 CFR 1.116 - Expedited Procedure

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June 16, 2003

PATENT APPLICATION  
Attorney's Docket No.: 2685.1003-001  
Expedited Procedure Reply under 37 CFR 1.116  
Technology Center 1600

*Handwritten:* 7/7/03

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: David A. Edwards and Jeffrey S Hrkach  
Application No.: 09/383,054 Group: 1615  
Filed: August 25, 1999 Examiner: Amy E. Pulliam  
For: STABLE SPRAY-DRIED PROTEIN FORMULATIONS

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REQUEST FOR RECONSIDERATION AND PETITION UNDER 37 C.F.R.1.181

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This is a Request for Reconsideration and Petition under 37 C.F.R.1.181 of the Examiner's decision to refuse entry of the Amendment dated May 14, 2003. This request and petition is being filed within two months of receipt of the Advisory Action dated May 28, 2003. No fees are required for this paper.

09/383,054

-2-

The Amendment dated May 14, 2003 amended the claims to recite that the particles "consist" of stabilized protein, a phospholipid and, an optional buffer salt, thereby incorporating limitations of the first presented dependent claim. For example, Claim 50 was amended to include the limitation of Claim 51. The independent claims prior to the amendment recited that the particles "consist essentially of" these same components. The Amendment further canceled two claims (which recited these very limitations) and changed the dependencies of others.

The Amendment was filed to further emphasize the earlier arguments made by Applicants that the claims did not embrace the additional components employed in the products of Durrani (relied upon by the Examiner in the rejection) necessary to promote spontaneous liposomal formation *in vivo*.

It is noted that the original claims also presented claims which recited that the particles "comprise", "consist essentially of" and "consist of" the listed components. See, for example, Claims 1, 2 and 3, respectively, and Claims 26, 27 and 28, respectively. In the first Amendment, dated September 26, 2000, the claim set was replaced with a clean claim set, commencing with Claim 50. Even in that claim set, claims were presented with the different transitional phrases. Thus, claims presenting the phrase "consisting essentially of" and "consist of" were presented in Claims 50 and 51, for example.

Further, Applicants specifically argued in the response to the first Office action that Durrani adds additional components to its method to achieve liposomal formation not present in the claimed invention. See page 7, the last paragraph, line 6 et seq. The argument is highlighted in the paragraph bridging pages 8-9. The amendment to Claim 50, for example, was selected because the Examiner completely ignored these arguments in issuing the final rejection. Please note MPEP 707.07.

The Advisory Action dated May 28, 2003 states that the amendment is refused as it raises "new issues that would require further consideration and/or search." It goes on to state that

Applicant has amended the claims to more restrictive language. The independent claims now use consisting of language for the particles, rather than consisting essentially of language used earlier in prosecution. However, this amendment greatly changes the scope of the current claims, and requires further search and/or consideration to consider the allowability of the claims. The examiner has not searched the claims with this more narrow, restrictive language.

09/383,054

-3-

With respect to the Examiner's statement, Claim 50, as amended, corresponds in scope to Claim 51, canceled by the amendment. Other claims were amended similarly. These claims should have been examined previously. The amendment was predictable, given the presentation of the claim language in every claim set presented to the Examiner, the prominent placement of the language (i.e., the first presented dependent claim), the emphasis on the language throughout the response to the non-final Office action and the difference it creates with respect to the prior art.

Thus, the Examiner's refusal to enter the amendment is inconsistent with the earlier statements in the record that claims presenting this language have been considered and examined.

Entry of the Amendment is requested.

In light of Applicants arguments of record, allowance is respectfully requested.

### CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in conditions for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned at (978) 251-3509.

Respectfully submitted,

ELMORE CRAIG, P.C.

By 

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